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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/788,937 | 02/27/2004 | Vasily L. Yarnykh | UNIV0217 | 9183 |

7590 01/17/2007
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| EXAMINER |
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SOLANKI, PARIKHA

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| ART UNIT | PAPER NUMBER |
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3737

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 01/17/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/788,937

Applicant(s)

YARNYKH ET AL.

Examiner

Parikha Solanki

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>8/16/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Applicant's claim of benefit from prior-filed US Patent Application No. 60/452,071 under 35 U.S.C. 119 (e) or 35 U.S.C. 120, 121 or 365 (c) is hereby acknowledged and accepted.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 16 August 2004 was filed after the mailing date of the patent application on 27 February 2004. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

3. The listing of references of Song et al and Parker et al in pages 2-3 of the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

4. Claim 16 is objected to because it contains a typographical error. Claim 16 recites "said selective inversion RF pulse said non-selective inversion RF pulse". Examiner suggests the claim be amended to include the word "and" before the phrase "said non-selective inversion RF pulse". Appropriate correction is required.

5. Claims 9 and 20 are objected to for reciting claims upon which they do not depend. Examiner suggests that Applicant amend claims 9 and 20 to explicitly list the detailed steps performed by the claimed machine executable instructions. Appropriate correction is required.

6. Applicant is advised that should claim 11 be found allowable, claim 12 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

7. Applicant is advised that should claim 30 be found allowable, claim 31 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application

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are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 1-13, 19 and 20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The method of claim 1 does not provide a useful, concrete or tangible result as set forth in the USPTO Interim Guidelines for Examination of Patent Applications and Subject Matter Eligibility, published on October 26, 2005, and as such is directed towards non-statutory subject matter. For further detail regarding the definition of a useful, concrete and tangible result, see: http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101_20051026.pdf

Claims 2-13, 19 and 20 are rejected in view of their dependence from claim 1, as the limitations recited in these claims fail to cure the statutory deficiencies of claim 1.

10. Claims 21-28 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 21-28 merely recite an electromagnetic pulse sequence, which constitutes a non-statutory natural phenomenon under the considerations set forth on page 55 of the USPTO Interim Guidelines for Examination of Patent Applications and Subject Matter Eligibility, published on October 26, 2005. For further detail, see:

http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101_20051026.pdf

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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12. Claims 1-4, 7, 9-12, 14, 15, 18-20 and 29-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Foo et al (US Patent No. 6,498,946).

Foo ('946) discloses a method and system for multi-slice image acquisition with black blood contrast, including steps for applying a non-selective inversion pulse, a slice-selective re-inversion pulse, and timing execution of a series of RF excitation pulses with fast spin echo (FSE) readout (col. 2 lines 4-12, col. 4 lines 36-43). Foo ('946) further discloses that FSE imaging may be performed over several patient breath-holds in order to successively acquire individual slice images (col. 1 lines 36-39). Foo ('946) also provides a predefined inversion time TI (col. 4 lines 41-42). Foo ('946) defines black blood imaging as a method wherein the inversion time is selected such that "the blood signal is close to the null point" (col. 1 lines 62-63). Foo ('946) discloses that the image data is acquired during mid-diastole, which constitutes synchronization with a selected phase of the cardiac cycle as claimed in the instant application (col. 5 lines 11-15). The anatomical slices imaged by Foo ('946) collectively comprise a slab, and image data is acquired for each spatial slice in an order that provides optimal blood signal suppression (col. 1 lines 56-62).

Foo ('946) provides means and components for acquiring and storing image data for each slice in a selected region to be imaged (col. 2 lines 25-26, col. 3 lines 23-25). Foo ('946) further provides a computer program and a computer system for storing and executing the program, which is capable of performing the black blood imaging method as described above (col. 3 lines 19-25, col. 5 line 59 – col. 6 line 16).

The system of Foo ('946) includes an MRI apparatus adapted for imaging a patient, a computer, a display, a memory, and a processor, all of which combine to perform the black blood imaging method discussed above (col. 3 lines 8-29).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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14. Claims 5, 6, 16, 17 rejected under 35 U.S.C. 103(a) as being unpatentable over Foo et al (US Patent No. 6,498,946). Foo ('946) substantially discloses all features of the present invention as discussed above. Foo ('946) is silent with respect to the type of inversion pulses used for the black-blood imaging method. It is known in the art that adiabatic inversion pulses can be rendered insensitive to RF field inhomogeneities. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to perform the method of Foo ('946) with adiabatic selective and non-selective inversion pulses, in order to reduce the effects of RF field inhomogeneities on the acquired images.

Foo ('946) additionally fails to specify that the non-selective inversion pulse is a rectangular pulse. Applicant does not provide any patentable advantage in using a rectangular non-selective inversion pulse during black-blood imaging. Furthermore, the use of a rectangular pulse as the non-selective inversion pulse during double inversion MR imaging is well known in the art. Therefore, it would have been an obvious matter of design choice to one of ordinary skill in the art at the time of invention to use a rectangular non-selective inversion pulse while performing the method of Foo ('946).

15. Claims 8, 13 and 33-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foo ('946) in view of Fayad et al (Noninvasive In Vivo Human Coronary Artery Lumen and Wall Imaging Using Black-Blood Magnetic Resonance Imaging. *Circulation*. 200: pp.506-510. 2000.).

Regarding claims 8 and 13, Foo ('946) substantially discloses all features of the present invention as discussed above. Foo ('946) fails to teach that the imaged slices include at least one artery. In the same field of endeavor, Fayad (2000) teaches that black-blood MRI may be used to image the coronary artery and lumen wall in order to detect the presence of atherosclerotic plaque (Abstract). It would have been obvious to one of ordinary skill in the art at the time of invention to apply the method of Foo ('946) to include at least one artery in the imaged slices for detecting the presence of atherosclerotic plaque, in view of the teachings of Fayad (2000).

Regarding claims 34-40, Foo ('946) teaches a method of black blood imaging including the steps of applying selective and non-selective inversion RF pulses, waiting an inversion time TI, executing a sequence of RF pulses for imaging a single slice, and subsequently imaging a plurality of slices within a slab such that the magnetization signal for the flowing blood is close to null (col. 1 lines 36-39, col. 1 lines 62-63, col. 2 lines 4-12, col. 4 lines 36-43). Foo ('946) teaches the method for use in cardiac imaging, and additionally teaches the use of T2 contrast weighting (Abstract, col. 5 lines 59-61). Foo ('946) fails to provide specific steps for identifying a

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plurality of slices which are transverse to the longitudinal direction of the blood vessel being imaged and steps for imaging atherosclerotic plaque. Fayad (2000) teaches a method of MR black blood imaging for assessing the morphology of coronary atherosclerosis, and further teaches that the method may be performed with proton-density or T2 contrast weighting in order to characterize the components of detected coronary plaque (p. 509 col. 2). Fayad (2000) shows that the acquired image slices are transverse to the longitudinal direction of the blood vessel, in which atherosclerotic plaque is clearly visible (Figs. 3 and 4). Fayad (2000) further shows the demarcation of the right and left ventricles and the RV outflow tract, equivalent to index locations as claimed in the instant application (Figs. 3 and 4). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Foo ('946) to further include the weighting scheme of Fayad (2000) in order to detect and classify atherosclerotic plaque in one or more coronary blood vessels of a patient.

16. Claims 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foo ('946) in view of Fayad et al (Noninvasive In Vivo Human Coronary Artery Lumen and Wall Imaging Using Black-Blood Magnetic Resonance Imaging. *Circulation*. 200: pp.506-510. 2000), further in view of Kholmovski et al (A Generalized k-Sampling Scheme for 3D Fast Spin Echo. *Journal of Magnetic Resonance Imaging*. 11: pp. 549-555. 2000).

Foo ('946) and Fayad (2000) substantially teach all features of the present invention as applied to claims 34-40 above. Fayad (2000) additionally teaches that the method may include steps for reformatting the image in any desired plane direction, which includes an oblique slice as claimed in the instant application (p. 509 col. 2). Neither Foo ('946) nor Fayad (2000) teaches the use of multiplanar reformation or minimal intensity projection algorithms for producing the black blood image from the acquired image data. In the same problem solving area, Kholmovski (2000) teaches that multiplanar image reformation and minimum intensity projection algorithms may be used to create 2D reprojections of fluid circulation in an anatomical section in order to improve the diagnostic quality of the acquired images (p. 549 col. 1, p. 554 col. 2). It would have been obvious to one of ordinary skill in the art at the time of invention to further modify the combined method of Foo ('946) and Fayad (2000) to further include the steps of performing multiplanar reformation or minimal intensity projection algorithms on the acquired data, in order to more accurately detect and classify atherosclerotic plaque in the generated black blood images, in view of the teachings of Kholmovski (2000).

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parikha Solanki whose telephone number is 571.272.3248. The examiner can normally be reached on M-F, 8 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PS

Parikha Solanki

Examiner - Art Unit 3737

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